# PCLYHEME COMMUNITY MEETING FEEBAUK FORM

Please circle your answers
1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?
Yes No
2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?
Yes No
3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?  Yes  No
4. Do you have any comments or concerns you wish to share with the investigators?
Age: 36 Ethnic background: African American
Gender: Male Female

FLEDDACE FORM
Download and save this Microsoft Word document. Fill out the document, and e-mail it to Arletta.vanbreda@inova.com.

1. Would you support conducting a study such as the one described in this community, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent? (Type Yes or No in the space below)

YES

2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study? (Type Yes or No in the space below)

YES

3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study? (Type Yes or No in the space below)

YES

4.	Do you have any comments or concerns you wish to share with the investigators?		
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Ag	e:50	Ethnic background: Caucasian	
Ge	nder: Male	Female _X	

Download and save this Microsoft Word document. Fill out the document, and e-mail it to <u>Arletta.vanbreda@inova.com</u>.

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YES

3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study? (Type Yes or No in the space below)

YES

4. Do you have any comments or concerns you wish to share with the investigators?

Yes I think you are way behind in getting started. I would have thought that being No VA is at the forefront of technology you would have been at the front of this trial not at the back. But hey better late than never. Loudoun Resident		
Age: _42	Ethnic backgroundwhite	
Gender: Male X	Female	

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1.	Would you support conducting a study such as the one described in this	community,
spo	ecifically, a study in which severely injured and bleeding patients would l	oe enrolled
wi	thout giving their informed consent? (Type Yes or No in the space below	)

YES

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YES

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YES

4.	Do you have any comments or concerns you wish to share with the investigators?		
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M			
Ag	e:50	Ethnic background: Caucasian	
Gei	nder: Male	Female X	

#### ADLYHEME COMMUNITY MEETING FEEBACK FORM

1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?

Yes No

2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?

Yes No

3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?

Yes No

4. Do you have any comments or concerns you wish to share with the investigators?

Thank you for your participation today. Please call Arletta VanBreda at 703-504-3071 if you have any other questions.

Ethnic background:

Gender: Male Female

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1.	Would you support conducting a study such as the one described in this	community,
spo	ecifically, a study in which severely injured and bleeding patients would	be enrolled
wi	ithout giving their informed consent? (Type Yes or No in the space below	•)

Yes

2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study? (Type Yes or No in the space below)

Yes

3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study? (Type Yes or No in the space below)

Yes

4.	. Do you have any comments or concerns you wish to share with the investigators?		
Ag	e: _58	Ethnic background:	
Ger	nder: Male _X	Female	

#### FEEW BACK FURM

Download and save this Microsoft Word document. Fill out the document, and e-mail it to Arletta.vanbreda@inova.com.

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#### Yes

2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study? (Type Yes or No in the space below)

#### Yes

3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study? (Type Yes or No in the space below)

#### Yes

Male

Gender:

4. Do you have any comments or concerns you wish to share with the in		ny comments or concerns you wish to share with the investigators?
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Δα	e· 43	Ethnic background: Middle Eastern

Download and save this Microsoft Word document. Fill out the document, and e-mail it to <u>Arletta.vanbreda@inova.com</u>.

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Yes
4. Do you have any comments or concerns you wish to share with the investigators?
Age: _50 Ethnic background: White
Gender: Male X Female

Download and save this Microsoft Word document. Fill out the document, and e-mail it to <u>Arletta.vanbreda@inova.com</u>.

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YES

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PROGRAMME AND ADMINISTRATION OF THE PARTY OF	
Age: _42	Ethnic background white
Gender: Male	X- Female

Download and save this Microsoft Word doc	ument. Fill out the document, and e-
mail it to Arletta.vanbreda@inova.com.	

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4.	Do you have any com	ments or concerns you wish to share with the investigators?
-		
Age Ger	e: _25 nder Female	Ethnic background: Caucasian

Download and save this Micro	soft Word document	. Fill out the	document,	and e-
mail it to Arletta.vanbreda@in	ova.com.			

1.	Would you support conducting a study such as the one described in this community	/,
spe	cifically, a study in which severely injured and bleeding patients would be enrolled	
wit	hout giving their informed consent? (Type Yes or No in the space below)	

yes

Gender Female

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4.	Do you have a	ny comments or concerns you wish to share with the investigators?
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Aos	25	Ethnic background: Caucasian

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YES

4.	Do you have any co	mments or concerns you wish to share with the investigators?	
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	and the state of t		
			-
Ag	e:33_	Ethnic background:Caucasian	
Ge	nder: Male	FemaleX	

# FEE: BACK FORM

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yes
4. Do you have any comments or concerns you wish to share with the investigators?
Age: _41 Ethnic background: White
Gender: Male Female x

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  Yes
- 2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study? (Type Yes or No in the space below)

Yes

3. If a family member of yours were severely injured and bleeding and were to be treated
by the paramedics, would you want him or her to be enrolled in this type of study? (Type
Yes or No in the space below)
Yes

4. Do you have any comments or concerns you wish to share with the investigators?

Age: 26 Ethnic background: Black

Gender: Male \_\_\_\_ Female X

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1. Would you support conducting a study such as the one described in this community, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent? (Type Yes or No in the space below)

#### YES

2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study? (Type Yes or No in the space below)

#### YES

3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study? (Type Yes or No in the space below)

#### YES

4. Do you have an	ny comments or concerns you	wish to share with the inv	estigators?
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Florida (Children) - The second of the Children Children Children Children			
Age: _31_	Ethnic background:	Caucasian	
Gender: Male	X Female		

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1.	Would you	u support	conducting a	study such	as the c	one described	in this	community,
sp	ecifically, a	a study in	which severe	ly injured	and blee	ding patients	would	be enrolled
wi	thout givin	g their in	formed conse	nt? (Type	Yes or N	o in the space	e below	·)

Yes

2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study? (Type Yes or No in the space below)

Yes

3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study? (Type Yes or No in the space below)

Yes

4. Do	you have any comments or concerns you wish to share with the investigators?
	erns. I think it's important to participate in studies such as these to improve the f medical treatments.
Age: <u>42</u>	Ethnic background: <u>Caucasian</u>
Gender:	Male Female X

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REGEI	ATTECO PARTICULAR PROCESSION VICTORIA
	Would you support conducting a study such as the one described in this community, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent? (Type Yes or No in the space below)
Yes	
you	f you were severely injured and bleeding and were being treated by the paramedics in r community, would you want to be enrolled in this type of study? (Type Yes or No in space below)
Yes	
by t	f a family member of yours were severely injured and bleeding and were to be treated he paramedics, would you want him or her to be enrolled in this type of study? (Type or No in the space below)
Yes	
4.	Do you have any comments or concerns you wish to share with the investigators?
-	
Marie L. Professor	
Age	: 44 Ethnic background: Caucasian
Gen	der: Male Female X

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yes
4. Do you have any comments or concerns you wish to share with the investigators?
I have less concern about using this product than I have over emergency use of blood supply in this day and time. The risks are reasonable.
Age: _61 Ethnic background:
Gender: Male Female x

COTA : enay

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#### § 50.24 If reeption from informed consent requirements for emergency research.

- (a) The Institutional Review Board (IRB) responsible for the review, approval, and continuing review of the clinical investigation described in this section may approve that investigation without requiring that informed consent of all research subjects be obtained if the IRB (with the concurrence of a licensed physician who is a member of or consultant to the IRB and who is not otherwise participating in the clinical investigation) fields and documents each of the following.
  - 1. The human subjects are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence, which may include evidence obtained through randomized placebo-controlled investigations, is necessary to determine the safety and effectiveness of particular interventions.
  - 2. Obtaining informed consent in not feasible because:
    - i. The subjects will not be able to give their informed consent as a result of their medical condition;
    - ii. The intervention under investigation must be administered before consent from the subjects legally authorized representatives is feasible; and
    - iii. There is no reasonable way to identify prospectively the individuals likely to become eligible for participation in the clinical investigation.
  - 3. Participation in the research holds out the prospect of direct benefit to the subjects because:
    - i. Subjects are facing a life-threatening situation that necessitates intervention:
    - ii. Appropriate animal or other preclinical studies have been conducted, and the information derived from those studies and related evidence support the potential for the intervention to provide a direct benefit to the individual subjects: and
    - iii. Risks associated with the investigation are reasonable in relation to shat is know about the medical condition of the potential class of subjects, the risks and benefits of standard therapy, if any, and what is known about the risks and benefits of the proposed intervention or activity.
  - 4. The clinical investigation could not practicably be carried out without the waiver.
  - 5. The proposed investigational plan defines the length of the potential therapeut ic window based on scientific evidence, and the investigator has committed to attempting to contact a legally authorized representative for each subject within that window of time and, if feasible, asking the legally authorized representative contacted for consent within that window rather than proceeding without consent. The investigator will summarize efforts made to contact legally authorized representatives and make this information available to the IRB at the time of continuing review.
  - 6. The IRB has reviewed and approved informed consent procedures and an informed consent document consistent with §50.25. These procedures and the informed consent document are to be used with subjects or their legally authorized representatives in situations where use of such procedures and documents is ferasible. The IRB has reviewed and approved procedures and information to be used when providing an opportunity for a family member to object to a subject's participation in the clinical investigation consistent with paragraph (a)(7(v) of this section.
  - 7. Additional protections of the rights and welfare of the subjects will be provided including, at least:
    - i. Consultation (including, where appropriate, consultation carried out by the IRB) with representatives of the communities in which the clinical investigation will be conducted and from which the subjects will be drawn;
    - ii. Public disclosure to the communities in which the clinical investigation will be conducted and from which the subjects will be drawn, prior to initiation of the clinical investigation, of plans for the investigation and its risks and expected benefits;

- iii. Public discussure of sur leient information following comparion of the cinical investigation to apprise the community and researchers of the study, including the demographic characteristics of the research population, and its results;
- iv. Establishment of an independent data monitoring committee to exercise oversight of the clinical investigation; and
- v. If obtaining informed consent is not feasible and a legally authorized representative is not reasonable available, the investigator has committed, if feasible, to attempting to contact within the therapeutic window the subject's family member who is not a legally authorized representative, and asking whether he or she objects to the subject's participation in the clinical investigation. The investigator will summarize efforts made to contact family members and make this information available to the IRB at the time of continuing review.
- (b) The IRB is responsible for ensuring that procedures are in place to inform, at the earliest fo asible opportunity, each subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, of the subject's inclusion in the clinical investigation, the details of the investigation and other information contained in the informed consent document. The IRB shall also ensure that there is a procedure to inform the subject, or if the subject remains incapacitated, a legally authorized representative of the subject, or if such a representative is not reasonably available, a family member, that he or she may discontinue the subject's participation at any time without penalty or loss of benefits to which the subject is otherwise entitled. If a legally authorized representative or family member is told about the clinical investigation and the subject's condition improves, the subject is also to be informed as soon as feasible. If a subject is entered into a clinical investigation with waived consent and the subject dies before a legally authorized representative or family member can be contacted, information about the clinical investigation is to be provided to the subject's legally authorized representative or family member, if feasible.
- (c) The IRB determinations required by paragraph (a) of this section and the documentation required by paragraph (e) of this section are to be retained by the IRB for at least 3 years after completion of the clinical investigation, and the records shall be accessible for inspection and copying by FDA in accordance with § 56.115(b) of this chapter.
- (d) Protocols involving an exception to the informed consent requirement under this section must be performed under a separate investigational new drug application (IND) or investigational device exemption (IDE) that clearly identifies such protocols and protocols that may include subjects who are unable to consent. The submission of those protocols in a separate IND/IDE is required even if an IND for the same drug product or an IDE for the same device already exists. Applications for investigations under this section may not be submitted as amendments under §§ 312.30 or 812.35 of this chapter.
- (e) If an IRB determines that it cannot approve a clinical investigation because the investigation does not meet the criteria in the exception provided under paragraph (a) of this section or because of other relevant ethical concerns, the IRB must document is findings and provide these findings promptly in writing to the clinical investigator and to the sponsor of the clinical investigation must promptly disclose this information to FDA and to the sponsor's clinical investigator who are participating or are asked to participate in this or a substantially equivalent clinical investigation of the sponsor, and to other IRB's that have been, or are, asked to review this or a substantially equivalent investigation by that sponsor.

HISTORY:

[61 FR 51493, 51529, Oct. 2, 1996]

was from

# QUESTION® AND ANSWERS POLYHEME® TRAUMA TRIAL

#### Why is this study being conducted?

To evaluate the life-saving potential of PolyHeme® when given to severely injured patients and bleeding patients, starting at the scene of injury

#### What is the title of this study?

A Phase III, Randomized, Controlled, Open-Label, Multicenter, Parallel Group Study Using Provisions for Exception from Informed Consent Requirements Designed to Evaluate the Safety and Efficacy of Poly SFH-P Injection [Polymerized Human Hemoglobin (Pyridoxylated) PolyHeme®] When Used to Treat Patients in Hemorrhagic Shock Following Traumatic Injuries Beginning in the Prehospital Setting

### What is the design of this study?

Patients in "hemorrhagic shock" will begin to receive either the standard of care (sal! water) (control) or PolyHeme (investigational treatment). Treatment would begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during a 12-hour postinjury period in the hospital.

In the hospital, patients in the control group will receive salt water for hydration and blood if necessary to boosts oxygen levels. Unlimited doses of each are allowed.

Patients in the treatment group will receive salt water for hydration and PolyHeme® to boost oxygen levels. The maximum dose of PolyHeme will be 6 units during first 12 hours. Blood will be used thereafter.

#### What is hemorrhagic shock?

Hemorrhagic means the patient has experienced massive blood loss Shock is a life-threatening condition that might include:

- Dangerously low blood pressure
- Internal organs don't receive enough oxygen and have difficulty functioning
- Might lead to death

Why is there a need for improvement in the way trauma patients are treated now?

Trauma is the leading cause of death among Americans under the age of 45.

What is the current stand and of the ? How are trauma patient usuall, stanted?

They are given saline solution (salt water) at the scene or in the ambulance. When they arrive at the hospital, they are given blood after typing and cross-matching is accomplished.

#### Who would be eligible for the study?

Patients who have lost a large amount of blood and are in shock Patients who are at least 18 years old Patients who have sustained severe injuries

#### Who would be excluded from the study?

Women who are obviously pregnant
Patients with severe brain injuries
Patients who require CPR to maintain their heartbeat
Patients with "unsurvivable" injuries
Patients who are known to object to blood transfusions
Patients who are known to refuse resuscitation

#### What is PolyHeme®?

PolyHeme® is an oxygen-carrying blood substitute made from human blood. PolyHeme® requires no cross matching, therefore it is immediately available and compatible with all blood types. PolyHeme® is highly purified to reduce the risk of viral disease transmission. It has an extended shelf life of over 12 months.

#### Is PolyHeme® safe?

In clinical trials to date,  $PolyHeme \otimes has$  demonstrated no clinically relevant adverse effects.

Past studies have shown that PolyHeme® carries as much oxygen as blood, has not caused organ damage, keeps people alive who have lost all of their own blood, and can be infused up to two times a person's entire blood volume.

#### Has PolyHeme® been tested on humans before?

There have been 5 human clinical trials of PolyHeme®.

#### How many patients have been treated with PolyHeme®?

Over 300 patients have been treated, including patients in a hospital-based trauma trial.

#### What happened to them?

In the Phase II hospital trauma trial, PolyHeme® significantly increased survival compared with historical controls.

#### What is an exception from informed consent?

Regulations established by the Federal government, (21 Code of Federal Regulations 50.24) specifies the conditions under which an exception from informed consent so that in emergency situations, research can be carried out even when consent is not possible because of the nature and extent of the patient's injuries.

#### Why was such an exception granted in connection with this study?

Patients are in a life-threatening situation, available treatments are unproven or unsatisfactory, and the collection of valid scientific evidence is necessary to determine the safety and effectiveness of particular interventions.

Participating in the study has the prospect of direct benefit to the enrolled patients because:

- Patients are in a life-threatening situation that necessitates intervention
- Previous studies demonstrate the potential to provide a direct benefit to enrolled patients
- Risks associated with the use of the PolyHeme® are reasonable in relation to what is known about the patients' medical condition, the risks and benefits of standard therapy, and the risks and benefits of the proposed intervention

It is expected that patients will be unable to give informed consent because the extent of their injuries and the fact that they are in shock.

There won't be time to find and ask for consent from the patient's legally authorized representative (LAR) before beginning treatment.

#### Who grants such exceptions?

The U.S. Food and Drug Administration (FDA) under regulations called 21 Code of Federal Regulations 50.24 specifies the conditions under which an exception from informed consent may be obtained. The Institutional Review Board (IRB) associated with each hospital approves its use locally.

#### What if patients don't want to participate in this study?

Patients can withdraw from the study at any time by notifying the investigator.

Will patients still receive treatment if they don't want to participate in the study?

Patients will still receive the standard of care if they decline to participate in this study.

# What are the potential benefits of participating in the study?

PolyHeme® may increase the likelihood of survival after traumatic injury.

Patients might avoid the risks of blood transfusion.

Patients might avoid a reduction in the function of internal organs that sometimes follows blood transfusion.

This study may help patients in the future.

# What are the potential risks of participating in the study?

Rash
Increased blood pressure
Kidney or liver damage
Transmission of hepatitis and HIV viruses
Unforeseen happenings

### How much will it cost patients to participate?

There is no charge to the patient to participate in this study. The study sponsor will pay the costs of certain laboratory tests that are required.

# Will patients get paid to participate?

No, patients will not be paid to participate in this study.

# Who is the manufacturer of PolyHeme®?

Northfield Laboratories Inc., Evanston, IL. For more information, visit www.northfieldlabs.com

Q!!

# PolyHeme<sup>®</sup> Trauma Trial

Community Consultation

Inova Regional Trauma Center Inova Fairfax Hospital Falls Church, VA

# Clinical Investigators

- Samir M. Fakhry, MD, FACS
  Cuief, Trauma Services
  Inova Regional Trauma Center
  Associate Chair for Research and Education
  Department of Surgery
  Inova Faurfax Hospital
- Christopher P. Michetti, MD, FACS General Surgery, Trauma, & Surgical Critical Care Luova Regional Trauma Center Inova Fairfax Hospital
- Trauma Services
   3300 Gallows Road
   Falls Church, VA 22042
   703-776-2274

# Study Sponsor

Northfield Laboratories Inc.

- Developer of the oxygen-carrying blood substitute called PolyHeme<sup>®</sup>
- Conducted multiple studies with PolyHeme over the past decade
- Most studies have been with injured trauma patients
- Company website: www.northfieldlabs.com

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# Study Purpose

To evaluate the life-saving potential of PolyHeme® when given to severely injured and bleeding patients in "hemorrhagic shock," starting at the scene of injury

# What is Hemorrhagic Shock?

Hemorrhagic: massive loss of blood

Shock: life-threatening condition

- · Dangerously low blood pressure
- Internal organs don't receive enough oxygen and have difficulty functioning
- · Might lead to death

# Need for Improved Outcome

- The Center for Disease Control (CDC) lists trauma as the leading cause of death among Americans under age 45
- Thousands of trauma patients die each year
- Many of these patients die because the "standard of care" cannot reverse the damaging effects of hemorrhagic shock

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What is the Standard of Care?	
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The patient receives  salt water  (blood is not available)  The patient receives  salt water  and donated blood	
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Standard of Care Limitations	
In the Ambulance	ang districtions of different interval parameters in the constraint different and a constraint in the
Salt water does not carry oxygen, unlike	
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Without enough oxygen, the body and its internal organs have difficulty functioning and can stop working (organ failure)	
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Standard of Care Limitations	
In the Hospital	
Donated blood takes time (45-60 minutes) to be matched for each patient	
Patients who receive more than 6 units of donated blood in the first 12 hours have an	
increased risk of organ failure	

# What is PolyHeme®?

A blood substitute that carries oxygen

1 unit of PolyHeme

1 unit of blood



# What is PolyHeme®?

- Made from human blood
- Compatible with all blood types
- · Immediately available
- Reduced risk of viral disease (viral load reduced over a billion times)



# Why Use PolyHeme®?

- PolyHeme was developed to treat blood loss when blood is not available
  - Blood is not available in the ambulance
  - PolyHeme will be immediately available in the ambulance and carcies oxygen
- PolyHeme can reduce the use of donated blood in the first 12 hours after injury, and might avoid potential organ failure

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# Why Use PolyHeme®? To improve survival of severely injured and bleeding patients PolyHeme® Experience · PolyHeme has been studied in more than 300 individuals and 5 different clinical trials · PolyHeme has been extensively studied in hospitalized trauma patients • PolyHeme has kept trauma patients alive when they have lost all of their own blood PolyHeme® Experience Past studies have shown that PolyHeme • Carries as much oxyger as blood (1 unit of PolyHeme = . unit of blood) · Reduces need for donated blood · Has not caused organ damage • Has replaced up to two times a person's entire blood volume (2 x 10 units = 20 units)

# Trial Design: Before the Hospital Severely injured trauma patients will be assigned to either one of two groups by chance Control Test Receive salt water Receive PolyHeme® Ambulance Infusion Trial Design: At the Hospital ControlTest · Salt water for " Salt water for hydration hydration Donated blood to " PolyHeme® to boost oxygen levels boost oxygen levels Maximum dose of 6 units during first 12 " Donated blood will be

used thereafter

# Hospital Infusion









# Who Would Be Included?

#### Patients at risk of dying

- · Who have sustained severe injuries
- Who have lost a large amount of blood and are in shock
- · Who are at least 13 years old
- Who are of either gender (male or female)

# Who Would Be Excluded?

- Patients who are obviously pregnant
- Patients who have severe head or brain injuries
- Patients who have "unsurvivable" injuries
- Patients who require CPR
- Patients with known objections to blood transfusions
- Patients with known orders not to resuscitate

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#### FDA Review

- Northfield Laboratories received clearance to proceed with this study from the Food and Drug Administration (FDA)
- The FDA authorized the use of an exception from informed consent requirements for this study

#### What is Informed Consent?

A process by which patients make informed decisions about participating in research studies

- · Traditionally required for all research studies
- Research studies compare 2 treatments (standard vs. investigational)
- Doctors describe each of these potential treatments

# What is Informed Consent?

A process by which patients make informed decisions about participating in research studies

- Patients are informed of the potential risks and potential benefits associated with each of these treatments
- Patients choose whether to participate in the study

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# What is Exception from Informed Consent?

Patients are enrolled in a research study without giving their informed consent

#### How Can That Be?

A federal regulation (21 CFR 50 24), created in 1996, allows certain studies that meet the following criteria to use this exception

- · Patients' lives must be at risk
- · Available treatments are not satisfactory
- · Patients are unable to give consent
- · Potential risks are reasonable

#### How Can That Be?

A federal regulation (21 CFR 50.24), created in 1996, allows certain studies that meet the following criteria to use this exception

- Participation in the research could provide a direct benefit (increased survival) to the patient
- The research could not be practicably carried out without an exemption

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# Consent Safeguards

- If possible, the patient or a legally authorized representative (LAR) can give consent before the patient is enrolled in the study
- If consent cannot be obtained before enrollment, frequent attempts will be made to contact the patient's LAR and family to describe the study

# Consent Safeguards

The patient, family members, or a legally authorized representative may decide to withdraw the patient at any time

# Potential Benefits of PolyHeme®

- · Might increase the likelihood of survival
- Can enhance the amount of vital oxygen in the patient's blood
- Is compatible with all blood types
- · Is immediately available
- Has reduced risk of viral disease (viral load reduced over a billion times)

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# Potential Risks of PolyHeme®

- Rash
- · Increased blood pressure
- Kidney or liver damage
- Viral infection (HIV, hepatitis, etc.)
- · Unforeseen happenings

#### Patient Protection

The Institutional Review Board (IRB) is a group of medical, scientific, and nonscientific members of the community

- Reviews all proposals for research on humans
- · Assures patient safety
- · Monitors community feedback

# Patient Protection

- The IRB will decide whether or not to allow this hospital to participate in the PolyHeme<sup>®</sup> trial
- An independent data monitoring committee will oversee the trial
- The FDA will be kept informed of the trial's progress

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# If We Participate... • The results of the study will be revealed to the community after the trial has been completed • Those who do not wan: to participate in the study can [wear a special bracelet] to exclude themselves Questions or Comments?

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Dear:

I am writing to inform you about a research study that may be conducted at Inova Feirfax Hospital.

Inova Fairfax Hospital is one of few Level I trauma centers in the U.S. chosen to participate in a research study to evaluate the safety and efficacy of PolyHeme®, an oxygen-carrying blood substitute, in increasing survival of critically injured and bleeding patients. Study treatment will begin before arrival at the hospital, either at the scene of the injury or in the ambulance, and continue during the initial 12-hour post-injury period in the hospital. Since blood is not presently carried in ambulances, the use of PolyHeme® in these settings has the potential to address a critical unruet medical need by providing an oxygen-carrying solution where blood is currently not available. The study will compare the survival rate of patients receiving PolyHeme® to that of patients who receive the current standard of care, which is saline (salt-water) solution.

Because the patients eligible for this study are unlikely to be able to provide prospective informed consent due to the extent and nature of their injuries, the study will be conducted under federal regulations that allow for clinical research in emergency settings using an exception from the requirement for informed consent (21 CFR 50.24).

Review Board (WIRB). WIRB is a group of people who perform independent review of research. The traditional approval of a research study includes a requirement that informed consent be obtained from patients before enrollment can occur. Under the current regulations, the institutional review board responsible for the review, approval and continuing monitoring of a research study may give approval for patient enrollment in studies in emergency situations without requiring informed consent provided specific criteria are met. The patients must be in a life-threatening situation, and the experimental therapy being evaluated must offer patients the potential for direct clinical benefit in the form of increased survival.

Before enrollment can begin, the regulations require public disclosure of information about the study, including the potential risks and expected benefits. Consultation must also occur with representatives of the community where the study will be conducted and from which the study population will be drawn. The process is highly individualized and is tailored to the specific community and patient population involved. Our institution is beginning this process now. The purpose of this letter is to provide you with background information about this study.

PolyHeme<sup>®</sup>, manufactured by Northfield Laboratories Inc. of Evanston, Illinois, is a universally compatible, immediately available, oxygen-carrying blood substitute designed for use in urgent blood loss when blood is not immediately available. Northfield Laboratories has completed five human research studies over the past decade.

In addition, Northfield is corrently working with the U.G. Army for research purposed or use of PolyHemp on the battlefield, reflecting the potential utility of PolyHeme for the military and the Department of Defense.

We are excited to be included in this research study. Trauma-related injuries are a leading cause of death among Americans under 45 years old, according to the CDC's National Center for Injury Prevention and Control. In fact, almost one in five trauma patients nationally die from their injuries. We believe that if we can begin to treat these patients very early with an oxygen-carrying solution and keep their hemoglobin levels up, we might well see more survivors among trauma victims in our community.

Please feel free to contact me directly should you wish to discuss this study and the implications for our community. Please join the Inova Research Center and Inova Trauma Services in the Physician's Conference Center on the campus of Inova Fairfax Hospital on Monday, March 7<sup>th</sup>, Tuesday, March 15<sup>th</sup> or Tuesday, March 22<sup>nd</sup> to learn more about this research study. All meetings begin at 7:00 pm. Please also visit our web site at <a href="www.inova.org">www.inova.org</a> and look for the PolyHeme Trial under either Inova News or Health Information.

I can be reached by calling <u>703-504-3071</u>. In advanced I thank you for your interest and time.

If you do not wish to receive future mailings from Inova Health System, please contact us at 703-321-2511.

Sincerely yours,

Samir M. Fakhry, M.D. Principal Investigator

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Lincolnia Fellowship Club		Alexandria	VA	22308
Lincolnia Senior Center		Alexandria	VA	22312
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Mt. Vernon Chapter #3198 AARP	•	Alexandria	VA	22308
Peace Pardners		Alexandria I	VA	22306
Retired & Senior Volunteer Program		Alexandria	VA	22312
Saunders B. Moon Senior Citizens Club		Alexandria	VA	22314
St. Lawrence Senior Citizens Club		Alexandria	VA	22309
The Retired Enlisted Assoc. Sr. Citizens League		Alexandria	VA	22312
The Senior Citizens League		Alexandria	İVA	22314
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Primrose Club for Seniors		Annandale	VA	22003
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Braddock Senior Citizens Club		Annandale	VA	22003
Fairfax Chapter #737 NARFE		Fairfax	VA	22030
Jewish Adult Social Club		Fairfax	VA	22031
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The second in the second in Club		Alexandria	ĪVA	22306
Rotary International Alexandria Club Arlington Rotary Club	•	Arlington	VA	22210
The Falls Church Rotary Club	,	Falls Church	VA	22045
The Rotary Club of Herndon		Herndon	VA	20170
West Springfield Rotary Club		Springfield	VA	22152

Rosary-Clubs.

lotter

# - Church letters

Organization	Street Address	City	State	Zip
Abiding Presence Lutheran Church		Burke	lVa	22015
Abundant Life Family Church		Fairfax	Va	22030
Accotink Unitarian Universalist Church		Burke	Va	22015
Ambassador Bible Church		Falls Church	Va	22046
American Lutheran Church		Fairfax	Va	22032
Annandale Church of Christ		Annandale	Va	22003
Annandale United Methodist Church		Annandale	VA	22003
Arabic Bible Baptist Church		Fairfax Station	Va	22039
Arlington Spanish SDA Church		Falls Church	Va	22046
Arlington United Methodist Church		Arlington	VA	22204
Bahai Faith of Northern Va		Vienna	Va	22182
Barcroft Bible Church		Fairfax	iva	22031
Beth El Hebrew Congregation		Alexandria	Va	22304
Bethlehem Lutheran Church		Fairfax	Va	22031
Bible Way Church of Lord Jesus		Fairfax	Va	22030
Blessed Sacrement Community Church		Alexendria	VA	22302
Braddock Missionary Saptist		Fairfax	Va	22030
Bruen Chapel United Methodist Church		Fairfax	VA	22031
Burke Community Church		Burke	Va	22015
Burke Presbyterian Church		Burke	Va	22015
Burke United Methodist Church		Burke	Va	22015
Calvary Christian Church		Burke	Va	22015
Calvary Church of the Nazerene		Annandale	Va	22003
Calvary Hill Baptist Church		Fairfax	Va	22031
Capital Baptist Church		Annandale	Va	22003
Catholic Diocese		Fairfax	Va	22030
Center Islamic Information and Education		Falls Church	Va	22046
Central Christian Church		Springfield	Va	22150
Central Presby Ch of Virginia		Fairfax	Va	22030
Chabad Lubavitch		Fairfax	Va	22031
Chabad Lubavitch of Alexandria		Alexandria	Va	22304
Chesterbrook Presbyterian Church		Falls Church	Va	22043
Chinese Christian Church		Falls Church	Va	22041
Christ Crossman United Methodist Church		Falis Church	Va	22046
Christ Lutheran Church Elca		Fairfax	Va	22030

Location	Hospital	Qty	Contact Person (If Applicable)	Comments
i				
IFH Shuttle Buses	IFH	10	Greg Austin	Allowed us to post one on each shuttle bus
IFH Science Library	IFH	5	Wendy & Director Approval	Allowed us to place in the seating area
Inova Research Center,	IFH	2	Lisa Collins/Jean Donovan	Hung on doors that enter the two research areas
IFH Posting by Hospital Elevators	1FH	6	Nancy O'Shea	Allowed us to post in all pre-existing elevator posting areas
ER	! IFH	?	Karen Peck	Still pending response from Karen- PhoduER-D+M
		_		Others are using the space now - they only allow 1 posting at a time to run and the current one is running
Gift Shop	- IFH	. 0.	Sara Freedenthal	until May.
ICU	IFH	4	Marjorie Avery	
OR	IFH	3	Caroline	
Deli	IFH	3	Deli Owner	Allowed us to post in windows
Cafeteria	IMVH	3	Rita Wakefield	dore
Flyer Boards	IMVH	11	Rita Wakefield	done all
Patient Care Unit Boxes	IMVH	Each	Rita Wakefield	ideal
Unit Posting/Department Posting	IFH	Each	Erica Neufeld	durk
Dept Mailboxes	IFOH	Each	Michelle Conner	All
Staff Newsletter	IFOH	All Depts.	Michelle Conner	end Inova web

Hyer Distribution

Organization	Street Address	City	State	Zip
Lions Club of Annandale	. 1	Annandale	IVA	122003
Lions Club of Arlington	er-vitoroje	Arlington	VA V	22210
Fairfax Lions Club	Official and the second of the	Fairfax	VA	22038
CLIFTON LIONS CLUB	Ž.	Clifton	VA	20124
The Falls Church Lions Club	:	Falls Church	VA	22040
Merrifield Lions Club		Merrifield	IVA	22116
Springfield-Franconia Host Lions Club		Springfield	VA	22150

Thors Clubs

letter

# appointed officials

Name	Organization	Street Address	City	State	Zip
Anita Kapper			Fairfax	IVA	22030
Anthony Griffin	Fairfax County Executive		Fairfax	VA	22035
Barbara Lippa	Fairfax County Planning		Fairfax	VA	22035
Bridget Mulvihill Jennison			Fairfax	VA	22031
Bruce Napoli	Herndon Zoning		Herndon	VA	20172
Caili Yang			Vienna	VA	22182
Carig Gerhart	Prince William County Exec		Prince William	VA	22192
Carl Siversten	Herndon Planning Comm		Herndon	VA	20172
Carol Coryell	27 2 2 2	~	Centreville	IVA	20120
Catherine Chlanese	Fairfax County		Fairfax	VA	22035
Chief Charles Samarra	City of Alexandria		Alexandria	VA	22304
Chief Charlie Deane	Prince William Police		Prince William	VA	20192
Chief David Rohrer	Fairfax County Police		Fairfax	VA	22030
Chief Gary Mesaris	City of Alexandria		Alexandria	VA	22314
Chief James Clarke Jr.	City of Falls Church		Falls Church	VA	22046
Chief Mary Beth Michos	Prince William County Fire		Prince William	VA	22192
Chief Michael Neuhard	Fairfax County Fire		Fairfax	VA	22030
Chief Robert Murray	City of Falls Church		Falls Church	VA	22046
Dana Paige	Fairfax County Family Service		Fairfax	VA	22035
Daniel McKeever	City of Falls Church		Falls Church	VA	22046
David Bobzien	County Attorney		Fairfax	VA	22035
David Hudson	City of Fairfax	,	Fairfax	VA	22030
David Recor	City of Fairfax		Fairfax	VA	22030
David Rock	Falls Church Zoning		Falls Church	VA	22046
David West			Alexandria	VA	22310
Dean Montgomery	Health Systems Agency		Fails Church	VA	22042
Dr. Charles Konigsberg	Alexandria Health		Alexandria	VA	22314
Dr. Edward Kelly	Prince William Schools		Prince William	VA	22192
Dr. Gloria Addo Ayensu	Fairfax County Health		Fairfax	VA	22030
Dr. J. Martin Lebowitz			Mc Lean	VA	22101
Dr. Jared Florance	Prince William Health		Manassas	VA	20110
Earl Berner	City of Fairfax		Fairfax	VA	22030
Edna Cruz			Centreville	VA	20120
Edward Semonian	City of Alexandria		Alexandria	VA	22314
Elleen Fogarty	Alexandria Planning		Alexandria	VA	22314

Name	Organization	Street Address	City	State	Zip
Elly Doyle					
Fred Hoffman			Mc Lean	VA	22102
George Myers			Alexandria	VA	22306
George Stepp	City of Fairfax		Alexandria	VA	22309
Ignacio Pessoa	City Attorney	•	Fairfax	VA	22030
Jackie Henderson			Alexandria	VA	22314
James Mazur	Alexandria City Clerk		Alexandria	VA	22314
James Stratoudakis PhD.	Named Health Co.		Dunn Loring	VA	22027
James Sutton	Mental Health Services		Fairfax	VA	22035
James Zook		·	Herndon	VA	20171
Jerome Ziskind	Fairfax County Planning		Fairfax	VA	22035
Jerry Little			Falls Church	IVA	22046
John Clark			Clifton	VA	20124
John Frey			Springfield	VA	22151
John Ruthinoski	Fairfax County		Fairfax	VA	22030
Statement of the statem	Fairfax County Health		Fairfax	VA	22030
John Schoeberlein	Town of Vienna		Vienna	VA	22180
Judith Rosen	Fairfax County		Fairfax	VA	22035
Lee G. Draznin			Burke	VA	22015
Louise Armitage	City of Fairfax		Fairfax	ĪVA	22030
Margaret Kugler			Fairfax	VA	22032
Marilyn Cantrell			Oak Hill	VA	20171
Mariene Blum			Vienna	VA	22180
Martin Briley	Prince William County EDA		Prince William	VA	20192
Mary Ellen Shaw	City of Falls Church		Falls Church	VA	22046
Mary McWhorter			Clifton	VA	20124
Merni Fitzgerald	Public Affairs		Fairfax	VA	22035
Michelle Evans	City of Alexandria		Alexandria	VA	22314
Nancy Kader			Reston	VA VA	20191
Nancy Vehrs	Fairfax County BOS		Fairfax	IVA	
Paul Ebert	Commonwealth's Attorney		Prince William		22035
Philip Sunderland	Alexandria City Manager		Alexandria	VA	20109
Randolph Sengel	Commonwealth's Attorney		Alexandria	VA	22314
Rebecca Perry	Alexandria Public Schools		P) Advantage to the advantage of the contract	VA	22314
Richard Kaufman	Town of Herndon Alty		Alexandria	VA	22311
Richard Reppaport	City of Fairfax		Herndon	VA	20172
Entra destination to handle questioning for the form of the second of the second destination of the second of the	5 VILY CH I CHRICA		rairfax	VA	22030

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Richard Risk Rick Goff Robert Gehring Robert Greenburg Robert Salazar	Falls Church EDA		City
Rick Gaff Robert Gehring Robert Greenburg			
Robert Gehring Robert Greenburg			
Robert Greenburg			Fal
The state of the s			Res
KODEN SHAZAR	Deputy County Executive		Res
Robert Sisson	City of Fairfax		√Fai
Rosenn Tergis	Family Services		Fair
Rose Chu	T LITTING COLVINGS		Fair
Roseanne Rodilosso			Fall
Roy Thorpe Jr.	City of Falls Church		Fall
Sally Hottle	Joint Cit Caro Ortafor		Fall
Sarah Eissler			Spr
Sharon Kelso			Lori
Sharon Pandak	Prince William County Atty	*	King
Sheriff Glendell Hill	Prince William County		Prin
Sherman Patrick	Prince William Zoning		Prin
Stephan Griffin	Prince William Planning		Prin
Stephen Bittle	City of Falls Church		Prin
Stephen King	Çelebrate Fairfax Inc		Fall
Steve Owen	Herndon Town Manager		Fair
Susan Randall	The state of the s		Her
The Hon. A MacDonald			Spri
The Hon. Adam Ebbin			Alex Arlin
The Hon. Albert Elsenberg			
The Hon. Ann Null	Town of Herndon		Arili Hen
The Hon. Brian Moran			Alex
The Hon. Carol Bruce			JAIe) Hen
The Hon. Catherine Hudgins	Fairfax County BOS		· ·
The Hon. Chap Peterson			Res Fair
The Hon. Charles Colgan			S
The Hoh. Corey Stewart			Mar
The Hon. Dana Kauffman	Fairfax County BOS		Prin Alex
The Hon. Daniel Gardner	THE RESIDENCE OF THE PROPERTY		(agrantes
The Hon. Darryl Smith	Town of Herndon		Falls
The Hon. David Albo			Heri Spri

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Falls Church	VA	22041
Falls Church	VA	22046
Reston	VA	20190
Reston	VA	20191
Fairfax	VA	22035
Fairfax	VA	22030
Fairfax	VA	22035
Falls Church	VA	22041
Falls Church	VA	22043
Falls Church	VA	22046
Springfield	VA	22153
Lorton	VA	22079
Kingstowns	VA	22315
Prince William	VA	22192
Prince William	VA	22192
Prince William	VA	22192
Prince William	VA	20192
Falls Church	VA	22046
Fairfax	IVA	22035
Herndon	VA	20172
Springfield	VA	22153
Alexandria	VA	22314
Arlington	VA	22204
Arlington	VA	22210
Herndon	VA	20172
Alexandria	VA	22304
Herndon	IVA	20170
Reston	IVA	20190
Fairfax	VA	22030
Manassas	VA	20110
Prince William	VA	22192
Alexandria	VA	22310
Falls Church	VA	22046
Herndon	IVA	20172
Springfield	IVA	22152
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State Zip

Name	Organization	Street Address
The Hon. David Snyder		•
The Hon. Dennis Husch	Town of Herndon	-
The Hon. Edythe Kelleher	Vienna Town Council	_
The Hon. Elaine McConnell	Fairfax County BOS	
The Hon. Frank Wolf		_
The Hon. Gail Lyon		_
The Hon. Gary Rassmussen		
The Hon. Gary Reese		,
The Hon. George Allen		<b>-</b> -}
The Hon. George Lovelace	Vienna Town Council	
The Hon. Gerald Hyland	Fairfax County BOS	
The Hon. Gerals Connolly	Fairfax County BOS	
The Hon. Harlon Reece	Town of Herndon	
The Hon. Harry Parrish		
The Hon. Hilda Barg		,
The Hon. J Greenfield		
The Hon. James Dillard II		
The Hon. James Dunning	City of Alexandria	
The Hon. James Moran		1
The Hon. James Scott		·
The Hoḥ. Jane Seeman	Mayor, Town of Vienna	
The Hon. Janet Howell		•
The Hon. Jay O'brien		, 
The Hon. JeannMarie Develites		
The Hon. Jeffrey Frederick		
The Hon. Joan Cross		
The Hon. Joan DuBois	Fairfax County BOS	
The Hon, Joe May		· ·
The Hon. John Jenkins		
The Hon. John Stirrup		
The Hon. John Warner		
The Hon. Joyce Woodson		pa-Autoria
The Hon, K Rob Krupicka		
The Hop. Kenneth Cuccinelli		1
The Hon. Kenneth Plum		1

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Falls Church	VA	22046
Herndon	VA	20172
Vienna	VA	22180
Springfield	VA	22152
Washington	DC	20515
Fairfax	VA	22030
Fairfax	VA	22030
Oak Hill	VA	20171
Washington	DC	20510
Vienna	VA	22180
Alexandria	VĄ	22306
Fairfax	VA	22035
Herndon	VA	20172
Manassas	VA	20110
Woodbridge	VA	22191
Fairfax	VA	22030
Fairfax	VA	22032
Alexandria	VA	22314
Washington	DC	20515
Merrifield	VA	22116
Vienna	MA	22180
Reston	IVA	20195
Clifton	VA	20124
Vienna	VA	22183
Woodbridge	VA	22194
Fairfax	VA	22030
Mc Lean	VA	22101
Leesburg	VA	20177
Prince William	VA	22192
Manassas	VA	20109
Washington	DC	20510
Alexandria	VA	22301
Alexandria	ĪVA	22301
Centreville	TVA	20122
Reston	TVA	20191
L	<u> </u>	127121

State Zip

City

Name	Organization	Street Address	City	State	Zip
The Hon. Kristen Amundson			Mt Vernon	VA	22121
The Hon. Laurie Cole	Vienna Town Council		Vienna	VA	22180
The Hon. Linda Puller			Mt Vernon	VA	22121
The Hon. Linda Smyth	Fairfax County BOS		Fairfax	VA	22031
The Hon. Lindy Hockenberry			Falls Church	VA	22046
The Hon. Ludwig Gaines			Alexandria	VA	22314
The Hon. M Polycrones	Vienna Town Council		Vienna	VA	22180
The Hon. M Van Landingham			Alexandria	VA	22314
The Hon, M. Polychrones	Virginia Town Council		Vienna	VA	22180
The Hon. Mark Sickles			Alexandria	VA	22310
The Hon. Martha Meserve			Falls Church	VA	22042
The Hon, Martin Nohe			Woodbridge	VA	22192
The Hon. Mary M Wipple			Arlington	VA	22207
The Hon. Mary M. Whipple			Arlington	VA	22207
The Hon. Maud Robinson	Vienna Town Council		Vienna	VA	22180
The Hon. Maureen Caddigan			Woodbridge	VA	22191
The Hon. Michael Frey	Fairfax County BOS		Chantilly	VA	20151
The Hon. Micheal O'Reilly	Mayor of Herndon		Herndon	VA	20170
The Hon. Michele McQuigg	l	*	Occoquan	VA	22125
The Hon. Patrice Winter			Fairfax	VA	22030
The Hon. Patricia Ticer	3	•	Alexandria	VA	22314
The Hon. Paul Smedberg		•	Alexandria	VA	22314
The Hon, Penelope Gross	Fairfax County BOS	•	Annandale	VA	22033
The Hon. Redella Pepper		•	Alexandria	VA	22304
The Hon. Richard Black		•	Sterling	VA	20165
The Hon. Richard Saslaw			Springfield	VA	22151
The Hon, Robert Brink	-	•	Arlington	VA	22207
The Hon. Robert Horan Jr.	Commonwealth's Attorney	•	Fairfax	VA	22030
The Hon. Robert Hull		•	Fails Church	ĪVA	22042
The Hon. Robert Lederer	THE ART OF THE OWN BY THE PROPERTY AND T	•	Fairfax	ĪVA	22030
The Hon. Robert Marshall		-	Manassas	VA	20108
The Hon. Robin Gardner		-	Falls Church	VA	22046
The Hon, Ronald Parson		<u>.</u>	Falls Church	VA	22046
The Hon. Samuel Mabry	City of Falls Church	-	Falls Church	TVA	22042
The Hon. Scott Lingamfelter	The second secon		Woodbridge	TVA	22193
A sign a sold content with the sign of the		<del>,</del>	Leanning	TAU	14410

The Hon. Scott Silverthorne The Hon. Sean Connaughton			Fairfax	[VA	Lagona
The Hon. Sean Connaughton			Fairfax	N/A	LOCOCO
			<u> </u>		22030
	Im . r O 1 000		Prince William	VA	22192
The Hon. Sharon Bulova	Fairfax County BOS		Burke	VA.	22015
The Hon. Stanley Barry	Fairfax County Sheriff		Fairfax	VA	22030
The Hoh. Stephen Shannoh	;		Vienna	VA	22183
The Hon. Steve Briglia	Town of Vienna		Vienna	VA	22180
The Hon. Steven Mitchell	Town of Herndon		Herndon	VA	20172
The Hon. Sydney Verinder	Vienna Town Council	•	Vienna	VA	22180
The Hon. Thomas Davis III			Washington	JDC	20515
The Hon. Thomas Rust		,	Hemdon	VA	20172
The Hon. Tom Hugo		<del>.</del>	Centreville	VA	22194
The Hon. Vincent Callahan		-	Mc Lean	VA	22101
The Hon. Vivian Watts		<del>-</del> -	Annandale	VA	22003
The Hon. William Howell		<del>.</del>	Fredericksburg	VA	22405
The Hon. William Mims		<del>-</del>	Leesburg	VA	20178
The Hoh. Willian Euille	City of Alexandria	<del>-</del> -	Alexandria	VA	22301
The Hon. WS Covington		_	Manassas	VA	20109
Theresa Adcock Gaffney		-	Burke	VÁ	22015
Thomaş Geib	Prince William County CSB	-	Prince William	VA	22192
Thomas Owens	City of Fairfax		Fairfax	VA	22030
Timothy Yarboro MD			Herndon	VA	22071
Verdia Haywood	Deputy County Executive	_	Fairfax	VA	22035
Vivian Baltz	City of Fairfax	<del></del>	Fairfax	VA	22030
William Finerfrock			Springfield	VA	22153
William Roeder, Jr.	City of Fairfax	<del></del>	Fairfax	VA	22030
William Shoup	Fairfax County Zoning	<del>-</del>	Fairfax	VA	22035

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Organization		(C) (A A A A A
Organization		Street Address
Christ Presbyterian Church		
Christian Science Church		
Christian Science Church		
Christian Science Church		
Christian Way Baptist Street		
Church of Christ		
Church of God Hafzi-Ba		
Church of Jesus Christ of LDS		
Church of Jesus Christ of LDS	)	
Church of Jesus Christ of LDS		
Church of Religious Science		
Church of the Apostles		
Church of the Good Shepard		
Church of the Good Shepherd	United Methodist Church	
Church of the Nativity		
Columbia Baptist Church		
Community Church of God		
Community Church of God		
Community of Christ		
Congregation Olem Tikvah		
Crossroads Baptist Church		
Culmore United Methodist Chi		
Dunn Loring United Methodist	Church	
Ebenezer Korean Church		
Eckankar Center		
Epiphany Byzantine Catholic	Church	ı
Fair Oaks Church		
Fairfax Assembly of God	18.5.2.49.11	
Fairfax Baptist Church		
Fairfax Baptist Temple		
Fairfax Christian Church		
Fairfax Church of Christ		•
Fairfax Circle Baptist Church:		
Fairfax Community Church		
Fairfax Covenant Church		

Fairfax !	Va	22033
Springfield	Va	22151
Fairfax	Va	22030
Springfield	Va	22151
Falls Church	Va	22046
Springfield	Va	22150
Falls Church	Va	22046
Annandale	Va	22003
Burke	Va	22015
Falls Church	Va	22043
Fairfax	Va	22030
Fairfax	Va	22031
Burke	Va	22015
Vienna	VΑ	22181
Burke	Va	22015
Falls Church	Va	22016
Dunn Loring	Va	22081
Falls Church	Va	22041
Springfield	Va	22151
Fairfax	Va	22031
Bailey's Crossroads	Va	22041
Falls Church	Va	22041
Dunn Loring	Va	22081
Springfield	Va	22151
Annandale	Va	22003
Annandale	Va	22003
Fairfax	Va	22030
Fairfax	Va	22033
Fairfax	Va	22030
Fairfax	Va	22032
Fairfax	Va	22031
Fairfax	Va	22033
Fairfax	Va	22031
Fairfax	Va	22032
Fairfax	lVa	22030

State Zip

City

Organization	Street Address	City	State	Zip
Fairfax Korean Church		Iraidan	IVA	22030
Fairfax Presbyterian Church		Fairfax Fairfax	VA  Va	22030
Fairfax Seventh-Day Adventist		Fairfax	va Va	22030
Fairfax United Methodist Chr			IVa IVa	
Fairlington United Methodist Church		Fairfax		22030
FAITH		Alexandria	VA	22302
Faith Bible Presbyterian Church		Herndon	VA	20170
		Falls Church	Va	22043
Falls Church Church of Christ		Falls Church	Va	22046
<u> </u>		Falls Church	Va	22041
Falls Church Presbyterian Church		Falls Church	Va	22046
Fellowship of Christian Athlts		Fairfax	Va	22032
First Baptist Church		Springfield	Va	22150
First Baptist Church	-	Falls Church	Va	22081
First Baptist Church	**************************************	Springfield	Va	22150
First Baptist Church of Springfield		Springfield	VA	22150
First Baptist Church of Vienna		Vienna	VA	22180
First Presbyterian Church		Annandale	Va	22003
First Presbyterian Church		Burke	Va	22015
First United Methodist Church		Falls Church	Va	22042
Friendship United Methodist Church		Falls Church	<u> VA</u>	22042
Galilee Korean United Methodist Church		Falls Church	Va	22042
Galloway United Methodist Church		Falls Church	Va	22042
Gideon Korean Baptist Church		Fairfax	Va	22030
Glencarlyh Rd Baptist Church		Falls Church	Va	22041
Global Mission Church		Vienna	Va	22081
God Is Love Baptist Church		Falls Church	Va	22042
Good Shepherd Catholic Church		Alexandria	VA	22309
Grace Christian Reformed Church		Burke	Va	22015
Grace Presbyterian Church		Springfield	Va	22150
Graham Road United Methodist Church		Falls Church	Va	22042
Greater Little Zion Baptist		Falifax	Va	22032
Greater Pentecostal Tougle;		Falrfax	Va	22030
Harvect Chinese Christian Chr		Fairfax	Va	22031
Holy Cross Korean Episcopal Church		Falls Church	Va	22041
Holy Spirit Catholic Church		Annandale	Va	22003

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Organization	Street Address
	-
Holy Spirit Wesleyan Church	
Holy Trinity Lutheran Church	1
Hope Lutheran Church	]
Idylwood Presbyterian Church	<b>,</b>
Iglesia Bautista Hispana Emanuel	1
Iglesia Bautista la Gran	1
Iglesis de Dios de La Profecia	1
immanuel Bible Church	j
Immanuel Church on the Hill	1
Immanuel United Methodist Church	
Inglesia Adventista De Falls Church	]
Jehovah's Witness	Ţ
Jehovah's Witness	1
Jehovah's Villness	1
Jehovah's Witness	]
Jehovah's Witness	]
Jehovah's Witness	
Jerusalem Baptist Church	I
Jerusalem Korean Baptist	
John Calvin Presbyterian Church	
Jordan Korean Baptist Church	]
King of Kings Lutheran Church	]
Knox Presbyterian Church	1
Korean Evangelical Church	]
Korean Methodist Church	]
Korean Pilgrim Community Church	
Korean Presbyterian Church	]
Little River United Church of Christ	1
Living Sayior Lutheran Church	7
Lomax AME Zion Church	1
Lord of Choice Christian Church	1
Lord of Life Lutheran Church	1
Marantha Baotist Church	7
McLean Korean Presbyterian Church	<del>-</del>
Messish Presbyterian Church	-
manuscome and the second secon	-

Annandale	Va	22003
Falls Church	VA	22042
Annandale	Va	22003
Fails Church	Va	22043
Alexandria	VA	22309
Fairfax	Va	22031
Alexandria	VA	22306
Springfield	Va	22151
Alexandria	VA	22301
Annandale	Va	22003
Falls Church	Va	22046
Falis Church	Va	22041
Alexandria	Va	22301
Arlington	Va	22213
Fairfax	Va	22030
Sterling	Va	20164
Vienna	Va	22182
Fairfax Station	Va	22039
Fairfax	Va	22032
Annandare	Va	22003
Springfield	Va	22150
Fairfax	Va	22033
Falis Church	Va	22042
Falls Church	Va	22042
Annandale	Va	22003
Burke	Va	22015
Fairfax	Va	22032
Annandale	Va	22003
Fairfax Station	Va	22039
Arlington	VA	22206
Burke	Va	22015
Feirfax	MA	22032
Annandale	Va	22003
f/icLean	VA.	22101
Annandale	Va	22003

State Zip

City

Organization	Street Address	City	State	Zip
Messiah United Mehtodist Church	umana,	Springfield	IVA	22152
Metropolitan Community Church	Manage of the state of the stat	. Fairfax	Va	22030
Ministerios Cristianos Salem		Arlington	VA	22203
Mision La Experanza	<del></del>	Alexandria	VA	22306
Mission of Our Lady	<del></del>	Fairfax	Va	22030
Made. Calvary Baptist Church	<del></del>	Fairfax	Va	22030
Mstc Buddhist Center	<del></del>	Fairfax	Va	22032
National Evangelical Free Church		Annandale	Va	22003
National Gardens Baptist Church		Falls Church	Va	22042
Nativity Lutheran		Alexandria	ÍVA	22308
New Evangelical Church Intl		Falls Church	Va	22043
New Hope Church		Springfield	Va	22150
New Hope Fellowship		Fairfax	Va	22033
New Hope Fresbyterian Church	many garages at	Fairfax	Va	22030
New Life Open Bible Church		Springfield	Va	22150
New Mt Zoar Baptist Church		Fairfax	Va	22030
Northern Va Korean Presbyterian Church	i	Annandale	İVa	22003
Northern Virginia Mennonite		Fairfax	Va	22030
On Baptist Church		Springfield	Va	22151
Parkwood Baptist Church		Annandale	Va	22003
Peace Christian Center Church		Falls Church	Va	22042
Pender United Methodist Church		Fairtax	VA	22033
Pentecostal Church Lababia		Annandale	Va	22003
Pentecostal Holiness Church		Falls Church	Va	22046
Pleasant Valley United Methodist Church		Chantilly	VA	20152
Potomac District Council of the Assemblies of God		Fairfax	Va	22030
Prince of Peace Lutheran Church	;	Springfield	VA	22152
Providence Presbyterian Church		Fairfax	Va	22031
Pure Presbyterian Church		Fairfax	Va	22030
Ravensworth Baptist Church		Annandale	Va	22003
Rothem Presbyterian Church		Annandale	Va	22003
Saint Many of Sorrows Catholic Church		Fairfax	Va	22032
Second Baptist Church		Fails Church	Va	22042
Seoul Presbyterian Church		Fairfax Station	VA	22039
Shalom Presbyterian Church		Fairfax	Va	22631

Organization	Street Address	City	State	Zip
Shepherd's Heart Incorporated		Fairfax	Va	22030
Smith's Chapel United Methodist Church	<del></del>	Falls Church	Va	22043
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St John's United Methodist Church	,	Springfield	Va	22151
St Katherine's Greek Orthodox Church		Falls Church	Va	22041
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St Lukes United Methodist Church		Falls Church	Va	22043
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St Patrick's Episcopal Church		Falls Church	Va	22042
St Paui's Episcopal Church		Bailey's Crossroads	Va	22041
St Paul's Lutheran Church		Falls Church	Va	22043
St Philips Catholic Church		Falls Church	Va	22042
St Stephen: United Methodist Church		Springfield	Va	2215
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St. Andrew's Episcopal Church		Burke	VA	22015
St. Anthony's Catholic Church		Falls Church	VA	22041
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Organization	Street Address	City	State	Zip
United Baptist		Annandale	IVA	22003
United Korean Church		Annandale	Va	22003
University Church of Christ		Fairfax	Va	22032
Vietnamese Allianca Church		Dunn Loring	Va	22027
Vineyard Korean Church		Annandale	lVa	22003
Virginia Korean Baptist Church		Fairfax Station	VA	22039
Virginia Presbyterian Church		Alexandria	VA	22310
Warner Baptist Church		Bailey's Crossroads	Va	22041
Washington Apostolic Church		Fairfax	Va	22030
Washington Chodae Church		Fairfax	Va	22031
Washington Christian Church		Fairfax	VA	22039
Washington Saehan Korean Church		Annandale	Va	22003
Way of Faith Assembly of God		Fairfax	Va	22031
Word of Life Church Intl		Fairfax	Va	22032

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Picm:

Anne Stewart

ro:

Lise.Collins@inova.com

Date:

Thu, Mar 3, 2005 4:05 PM

Subject:

PolyHeme information

Hi Lisa - Mary Jane Oldham asked me to detail for you the many ways in which we have publicized your PolyHeme study and the accompanying community meetings. Working from the outside to the inside, the list includes:

- press release regarding community meetings

- press release regarding special news conference with Dr. Fahkry

- blurb in Management Update Weekly, repeated several times (Inova Management Team)

- blurb in all hospital newsletters, including Monday Rounds (IFH/IFHC/IHVI), Exchange (IAH), Exchange (IMVH), Oak Post (IFOH), repeated several times

- blurb in Checknotes (all employees)

As you can see, we have covered all of Inova's internal audiences multiple times, as well as the community via the press. If you have any other questions, or would like a sample of one of the above items to share with your board, please do not hesitate to contact me and I can provide one for you.

Anne Stewart Marketing Communications Inova Health System 8003 Forbes Place Springfield, VA 22151

Phone: 703.321.2907 Fax: 703.321.2956 anne.stewart@inova.com

CC:

MaryJane.Oldham@inova.com,Denitra.Johnson@inova.com

Fromi

Kathleen Thomas

To:

Inova All

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Date:

Mon, Mar 7, 2005 1:12 PM

Subject:

Inova in the news...

Be sure to watch your local news tonight on Channels 4, 5, and 9 for a story about a study in which the Inova Regional Trauma Center at Inova Fairfax Hospital will participate. The study will involve the use of PolyHeme, an investigational blood substitute used to treat severely injured and bleeding patients who are in shock.

Samir Fakhry, MD, chief, and Christopher Michetti, MD, trauma surgeon, Inova Regional Trauma Center at Inova Fairfax Hospital both spoke at a news conference explaining the study.

An additional story can be heard this afternoon on WAMU-FM Radio (88.5) between 4 and 6 p.m.

Kathleen Thomas
Media Relations Manager
Inova Health System
703-776-2811
kathleen.thomas@inova.com

Incvo Fairfax Hospital PolyHeme® Trauma Study

Inova Fairfax Hospital, Fairfax, VA, is one of a few Level I trauma centers in the United States considering participation in a research study of an investigational, potentially life saving blood substitute for severely injured patients who are bleeding and in shock. This study uses a provision for an exemption from informed consent requirements in accordance with federal regulations (21CRF 50.24) since it is anticipated that patients will not be able to provide consent due to the nature and extent of their injuries. Patients, their legally authorized representative, or family member will be notified at the earliest opportunity of their inclusion and the details of the research study.

Community meetings will be held at Inova Fairfax Hospital, Physician Conference Center on March 7

March 15

March 22

At 7 PM for all members of the community who are interested in learning more about this study and to offer feedback to representatives of the Inova Fairfax Hospital.

For more information check the web @: at www.inova.org and look for the PolyHeme Trial under either Inova News or Health Information, or call Arletta van Breda, RN, 703 504 3071

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Lisa Col S FAIRFAX ALL

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3/14/2005 S:16:19 PM

Subject: PolyHeme Community Meetings

Men. Conta

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Hi All,

Please join the Inova Research Center and Trauma Services for a community meeting on Tuesday, March 15th to discuss the PolyHeme Trial. The meeting will begin at 7:00 pm in the Physician's Conference Center. Additional information about this trial can be found at www.inova.org under Health Information.

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F. ye

- 12 3 5 L

We look forward to seeing you all there and thank you for your support in advance.

Lisa J. Collins Database Analyst 3300 Gallows Road Falls Church, VA 22042 Work # 703-776-6574 Pager # 703-660-2299

2000

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Kim Purry Fineres

VanBrada, Arlecta Io: 4/8/2005 2:23:31 PM Date: Subject: Re: polyheme ad

Hi Arletta,

El Tiempo Latino: March 18

Washington Post Express: March 14, 17, 21

Metro Herald: March 11, 18

Washington Examiner: March 10, 14, 17, 20

Korean Times: March 12, 14, 19, 21

Thanks, Kim

>>> Arletta VanBreda 4/7/2005 11:54:06 AM >>> Hi Kim;

May I obtain the information about the ad, the papers the frequency of the ad placement?

I need to submit this information to the IRB.

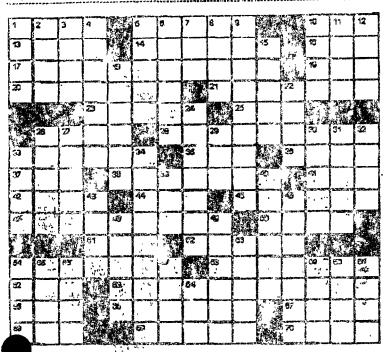
Many thanks

Arletta van Breda, R.N., MSN, CCRC Clinical Research Manager 703-504-3071 office 703-764-7310 ID# 73527 pager 703-504-3944 fax

arletta.vanbreda@inova.com

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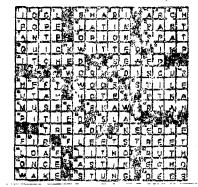
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Year's resolution 69 Prefix meaning "F. := 18 | 54"

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sispetick C4 4.0, maybe Friday's Solution



n some way, and you'll know it.

IANGER (Jene 21-Jely 22) Keep your vits about you, and be sure you take in all aformation before setting yourself free ind trusting in fate.

AG (July 23-Agg. 72) Domestic harmony an be achieved and maintained --- proided you do not allempt to prove your ioint in an inappropriate manner,

TROS (AME 23-POM. 22) You may be g similarities between yourself and d whom you consider unusual, re and weird. Lessons can be learned.

JSRA (Sept. 23-Ser. 22) If you've got it, launt it - but don't let others take undue dvantage of you. Someone you don't now may be looking for you.

IGONPIO (Get. 23-Kov. 21) Consider the

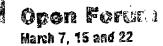
source before relying too heavily on outside Information. It's time once again for you to draw your own conclusions.

FARITYARIUS (P.Oz. 22-Eoc. 24) Travel. traval, travet. You are likely to be on the road again, and even more likely to enjoy a wealth of adventures along the way.

CAPERODIA (Doc. 22-Jes. IC) You may be lost on one or two pivotal occasions. Trust your right-hand man to see you through any difficult situations.

MUNASHUS (Jan. 26-feb. 16) Work with others to accomplish a single goal. You have things to contribute, se do they, and collectively you will get the job done well.

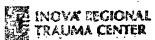
PISCES (Feb. 15-Seech 20) Take the time to evaluate an opportunity wisely and carafully before making a binding decision. You may be at a fork in the road.

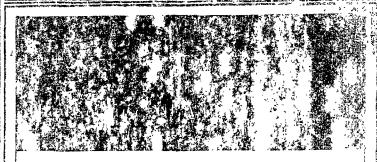


7 p.m. inova Feirfax Hospital Physicians Conference Center

Most with study investigator Samir Fakhry, MCL as he and the stully team discuss an investigntional blood substitute to be used in a respectit study for patients with sovere injuries who are bleeding or in shock, and involving an exception from informed consent requirements.

For more information, call 793-504-5071 or 3 vielt www.inave.org, and look for PolyHama tiel under kove never.





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With an Executive MBA from The George Washington University, you can be ready for tomorrow, sode year

### Upcoming Information Sessions:

In DC: Wed., March 23, 2005 at 6:30 PM

The George Washington University Club. 1918 F Street, NW. Washington, DC 20052

Mon., April 18, 2005 at 6:30 PM The Ritz Carkon, Tysons Comer 1700 Tysons Boulevard, McLean, VA 22102 Please register online at www.en.ba.g.-u.edu or call 1-808-£148A-GWQ









Research News

# COMMUNITY MEETINGS FOR CLINICAL TRIAL SCHEDULED

Inova Fairfax Hospital has been chosen to participate in a national clinical research study of PolyHeme®, an investigational oxygen-carrying blood substitute for trauma use. To comply with federal regulations, which permit this trial to be conducted without obtaining the informed consent of the patients enrolled, Inova Fairfax Hospital will hold three community meetings on Monday, March 7<sup>th</sup>, Tuesday, March 15<sup>th</sup>, and Tuesday, March 22<sup>nd</sup> all beginning at 7 p.m. in the Physician's Conference Center.

To learn more about this study, visit <u>www.ineva.or</u> and look for the PolyHeme Trial under either <u>Inova News</u> or <u>Hearth</u> <u>Information</u>.

### NEWS RELEASE - COMMUNITY MEETING

FOR IMMEDIATE RELEASE

CONTACT: NAME: Samir Fakhry, M.D. via Arletta van Breda, RN

PHONE 703 504 3071

EMAIL: arletta.vanbreda@inova.com

# INOVA FAIRFAX HOSPITAL INVITES THE PUBLIC TO ATTEND A COMMUNITY MEETING TO DISCUSS THE RESEARCH STUDY OF AN INVESTIGATIONAL BLOOD SUBSTITUTE IN TRAUMA PATIENTS TO BE CONDUCTED IN OUR COMMUNITY

Falls Church, VA-MONTH, DATE, YEAR —Trauma-related injuries are a leading cause of death in Americans under 45 years old, affecting more than 2 million persons annually. Nearly one in five trauma victims dies as a result of his/her injuries.

INOVA FAIRFAX HOSPITAL invites the public to attend community meetings at which members of its Trauma Service will explain the details of a national research study to evaluate an investigational blood substitute in severely injured and bleeding patients who are in shock. In this study, PolyHeme will be compared to the usual care. Study treatment would begin before arrival at the hospital, either at the scene of injury or in the ambulance, and continue through a 12-hour post injury period in the hospital. Only persons over 18 years of age who meet specific study criteria will be eligible for inclusion.

This research study is being conducted in accordance with federal regulations permitting an exception from informed consent requirements under 21 CFR 50.24. Samir Fakhry, M.D., will explain these regulations and the study protocol and the potential risks and benefits associated with participation. He will be available to answer questions. Your comments and concerns will be solicited and addressed.

The forum will take place on: March 7

March 15

March 22

In the Physician's Conference Center on the Inova Fairfax Campus at 7PM. Please review our web page at <a href="https://www.inova.org">www.inova.org</a> and look for the PolyHeme Trial under either Inova News or Health Information for more information.

Members of the media are invited to cover this event.

FOR IMMEDIATE PELEASE CONTACT: Dr. Samir Fakhry via Arletta van Breda, RN 703 504 3071 Or via the web page:

### CALENDAR ITEM/DAY, DATE

Inova Fairfax Hospital has been chosen to participate in a national clinical research study of PolyHeme®, an investigational oxygen-carrying blood substitute for trauma use. In this study, PolyHeme will be compared to the usual care. Study treatment would begin before arrival at the hospital, either at the scene of injury or in the ambulance, and continue through a 12-hour post injury period in the hospital. In order to comply with federal regulations which permit this trial to be conducted without obtaining the informed consent of the patients who will be enrolled, Inova Fairfax Hospital will hold three community meetings on March 7

March 15

March 22 @ 7PM in the Physician Conference Center on the campus of Inova Fairfax Hospital.

These meetings are being conducted to inform the public about the study and these regulations, to answer the public's questions, and to obtain feedback from public about the study. For further information, please visit their web page: at <a href="https://www.inova.org">www.inova.org</a> and look for the PolyHeme Trial under either Inova News or Health Information.

All interested staff and members of the community are invited to attend.

For Immediate Release March 1, 2005

Kathleen Thomas 703-776-2811

Beth Visioli 703-504-3438

# COMMUNITY INVITED TO ATTEND PUBLIC FORUM ON INVESTIGATIONAL BLOOD SUBSTITUTE

Inova Regional Trauma Center at Inova Fairfax Hospital
Will Participate in National Study of PolyHeme

Falls Church, VA- Trauma-related injuries are a leading cause of death in Americans under 45 years of age, affecting more than two million persons annually. Nearly one in five trauma victims in hemorrhagic shock dies as a result of his/her injuries.

The Inova Regional Trauma Center at Inova Fairfax Hospital invites the public to attend one of several community meetings to hear the details of a national research study to evaluate an investigational blood substitute in severely injured and bleeding patients who are in shock. In this study, PolyHeme will be compared to the usual care. Study treatment would begin before arrival at the hospital, either at the scene of injury or in transport, and continue through a 12-hour post injury period in the hospital. Only persons over 18 years of age who meet specific study criteria will be eligible for inclusion.

This research study is being conducted in accordance with federal regulations permitting an exception from informed consent requirements under 21 CFR 50.24. Samir Fakhry, MD, chief, trauma and critical care services, Inova Regional Trauma Center at Inova Fairfax Hospital, will explain these regulations and the study protocol as well as the potential risks and benefits

associated with participation. Dr. Fahkry will also be available to answer questions. Public comments and concerns will be solicited and addressed.

What: Community. Forum on Investigational Blood Study

When: March 7, 15, 22

7 p.m.

Where: Inova Fairfax Hospital

Physicians' Conference Center

3300 Gallows Road Falls Church, VA

Parking is available in the blue visitor's lot. The Physicians' Conference Center is located across the street from the garage.

For more information, please review our Web page at www.inova.org and look for the

PolyHeme Trial under Inova News or Health Information.

Inova Health System is a not-for-profit health care system based in Northern Virginia consisting of hospitals and other health services including emergency and urgent care centers, home care, nursing homes, mental health and blood donor services, and wellness classes. Governed by a voluntary board of community members, Inova's mission is to provide quality care and improve the health of the diverse communities we serve.

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For Immediate Release March 2, 2005

Kathleen Thomas, 703-776-2811 Beth Visioli, 703-504-3438

# INOVA REGIONAL TRAUMA CENTER AT INOVA FAIRFAX HOSPITAL TO HOLD NEWS CONFERENCE REGARDING ITS PARTICIPATION IN NATIONAL STUDY OF POLYHEME

## Blood Substitute Will Be Used To Treat Some Severely Injured Trauma Patients Who Are In Shock

Falls Church, VA – Trauma-related injuries are a leading cause of death in Americans under 45 years of age, striking more than two million people a year. Nearly one in five trauma victims in hemorrhagic shock dies as a result of his or her injuries.

Inova Regional Trauma Center at Inova Fairfax Hospital will soon begin participating in a national research study to evaluate an investigational blood substitute in severely injured and bleeding patients who are in shock. In this study, PolyHeme® will be compared to the usual care. Study treatment would begin before arrival at the hospital, either at the scene of injury or in transport, and continue through a 12-hour post-injury period in the hospital. Only people over 18 years of age who meet specific study criteria will be eligible for inclusion.

WHAT: News conference to discuss details of PolyHeme study

WHEN: Monday, March 7

10:30 a.m.

WHERE: Inova Regional Trauma Center at Inova Fairfax Hospital

3300 Gallows Road - Physicians Conference Center (lower level)

Falls Church, VA

WHO: Samir Fakhry, MD, chief, Trauma and Critical Care Services,

Inova Regional Trauma Center at Inova Fairfax Hospital

Inova Regional Cauma Center at Inova Fairfas Hospital will hold several community meetings to hear details of the national research study.

This research is being conducted in accordance with federal regulations permitting an exception from informed consent requirements under 21 CFR 50.24. Samir Fakhry, MD, chief, Trauma and Critical Care Services, Inova Regional Trauma Center at Inova Fairfax Hospital, will explain these regulations and the study protocol, as well as the potential risks and benefits associated with participation.

Media may park in the Blue Parking Garage located across from the Physicians
Conference Center.

Inova Health System is a not-for-profit health care system based in Northern Virginia that consists of hospitals and other health services including emergency and urgent care centers, home care, nursing homes, mental health and blood donor services, and wellness classes. Governed by a voluntary board of community members, Inova's mission is to provide quality care and improve the health of the diverse communities we serve.



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es	Schiavo	quality of life.	PolyHeme versus bloos in the hospital	50	Caucasian	F
			My only concern is that blood is denied			
i			to me in the hospital. I'd like to see			
i 			some data from the study showing that			
			being denied blood in these 12 hours			
es	Yes	Yes	wouldn't harm me.	27	Caucasian	F
	Yes	Yes		35	Caucasian	F
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			hospital, but I think research in this			
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/es	Yes	ÍYes		30	Caucasian	ĪF
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a you support conducting a study such gare described in this community,	bleeding and were being treated by the paramedica in your	of a family member of yours were severly injured and bleeding and were to be neated by the paramodes, would	Dave : how our comments or concern towards			en quante (C)" - para procesce com "mancroscation"
ുക്കിയ would be enrolled ്യിന്റെ their informed consent?	enrolled in this type of study?	this type of study?	Do you have any comments or concers you wish to share with the investigators?	Age	Ethnic Background	Gender
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			Talk to the lab more. We need real testing of product and how it effects	40	Causasian	F
	Yes	Yes	our test results	49	Caucasien	F
	Yes	Yes	t	F0	Causasian	F
TO STAND THE PARKET AND THE STAND TH	Yes	Yes			Caucasian	M
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	Yes	Yes		58	:	M
1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	Yes	Yes				M M
	Yes	Yes	Yes, I think you are way behind in	50		!VI
	Yes	Yes	getting started. I would have thought that being No VA is at the forefront of technology you would have been at the front of this trial not at the back, But hey better late than never. Loudoun Resident	42	Caucasian	M
	Yes	Yes			Caucasian	]F
	Yes	Yes			Caucasian	<u> </u> F
	Yes	Yes		41	Caucasian	F
	Yes	Yes			African American	F
A SA SECTION OF SALES	Yes	Yes	1	31	Caucasian	M
	Yes	Yes	No concerns. i think it's important to participate in studies such as these to improve the quality of medical treatments.	42	2 Caucasian	F
	Yes	Yes			Caucasian	F
,	Yes	Yes	I have loss concern about using this product than I have over emergency use of blood supply in this day and time. The risks are reasonable.		1 Caucasian	

	Please circle your answers
	1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?
(	Yes No
	2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?
(	Yes No
	3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?
(	Yes No
	4. Do you have any comments or corcerns you wish to share with the investigators?
	Age: ST Ethnic background:
	Gender: Male Female

Flease circle your unswers
1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?
Yes No
2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?
Yes No
3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?
Yes No
4. Do you have any comments or concerns you wish to share with the investigators?
Vone
Age: 39 Ethnic background: White

Thank you for your participation today.

Please call Arletta VanBreda at 703-504-3071 if you have any other questions.

Gender: Male \_\_\_\_ Female \_\_\_\_

Please circle your answers

·	ducting a study such as the one described in this community dy in which severely injured and bleeding patients would be eir informed consent?
Yes No	
,	ured and bleeding and were being treated by the paramedics in ou want to be enrolled in this type of study?
Yes No	
	ours were severely injured and bleeding and were to be treated you want him or her to be enrolled in this type of study?
Yes No	
4. Do you have any comm	nents or concerns you wish to share with the investigators?
Age: <u>43</u> Et	hnic background: White
Gender: Male F	emale <u>×</u>
<u></u>	
	hank you for your participation today.  mBreda at 703-504-3071 if you have any other questions.

Please circle your answers

meeting, spe	ou support conducting a study such as the one described in this community cifically, a study in which severely injured and bleeding patients would be nout giving their informed consent?
Yes	No .
2. If you we your commu	are severely injured and bleeding and were being treated by the paramedics in unity, would you want to be enrolled in this type of study?
Yes	No
3. If a famil by the param	y member of yours were severely injured and bleeding and were to be treated nedics, would you want him or her to be enrolled in this type of study?
Yes	No
4. Do you	have any comments or concerns you wish to share with the investigators?
Age: 64	Ethnic background:
·	Male 1 Female

Please circle your answers

1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?
Yes No
2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?
Yes No
3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?  Yes  No
4. Do you have any comments or concerns you wish to share with the investigators?  that no more ex consent is absolutely
that no mormed consent is absolutely
Nussaryo
Age: 42 Ethnic background: White
Gender: Male Female
Gender: Male Female

Please circle your answers 1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent? No Yes 2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study? No Yes 3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study? No Yes. Do you have any comments or concerns you wish to share with the investigators? None - all aucotions were

Thank you for your participation today. Please call Arletta VanBreda at 703-504-3071 if you have any other questions.

Gender: Male

Ethnic background: African-American

Please circle your answers

Gender: Male \_\_\_\_

1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?
Yes No
2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?
Yes No
3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?  Yes  No
4. Do you have any comments or concerns you wish to share with the investigators?
English persentation.
Age: 63 Ethnic background: Education

Please circle your answers	
1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?	
Yes No	
2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?	
Yes No	
3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?	
Yes No	
4. Do you have any comments or concerns you wish to share with the investigators?	
Age: 38 Ethnic background: Oneria	
Gender: Male Female X	

	Please circle your answers
	1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?
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	2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?
/ -	Yes No
``	3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?
(	Yes No
	4. Do you have any comments or concerns you wish to share with the investigators?  Way to Connected
	vo warm e tuzzer
	Age: Ethnic background: American
	Gender: Male Female
	Thenk you for your participation today

Please circle your answers

	1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?
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	2. If you were sever ted by the paramedics in your community, we udy?
	Yes No
_	3. If a family memb by the paramedics, we get and were to be treated is type of study?
	Yes No  4. Do you have any the investigators?
	4. Do you have any the investigators?
	Age: 50 Ethnic background: Laurasian
	Gender: Male Female

Please cir	rcle your answers
meeting,	I you support conducting a study such as the one described in this community specifically, a study in which severely injured and bleeding patients would be without giving their informed consent?
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	were severely injured and bleeding and were being treated by the paramedics in munity, would you want to be enrolled in this type of study?
Yes	No
	mily member of yours were severely injured and bleeding and were to be treated ramedics, would you want him or her to be enrolled in this type of study?
Yes	No
4. Do ye	ou have any comments or concerns you wish to share with the investigators?
A	
Age:	Ethnic background:
Gender:	Male Female
	Thank you for your particips; on today

# Please circle your answers 1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent? No 2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study? No 3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study? No Yes Do you have any comments or concerns you wish to share with the investigators? Age: 49

Thank you for your participation today. Please call Arletta VanBreda at 703-504-3071 if you have any other questions.

Gender:

Male

Please circle your answers

meeting, specifi	support conducting a study such as the one described in this community ically, a study in which severely injured and bleeding patients would be t giving their informed consent?
Yes	No
	severely injured and bleeding and were being treated by the paramedics in y, would you want to be enrolled in this type of study?
Yes	No
by the paramedi	nember of yours were severely injured and bleeding and were to be treated ics, would you want him or her to be enrolled in this type of study?
4. Do you hav	re any comments or concerns you wish to share with the investigators?
Age:	Ethnic background: CAVCASIAI
Gender: Male	Female
,	

Please circle your answers

	meeting, speci	support conducting a study such as the one described in this community ifically, a study in which severely injured and bleeding patients would be out giving their informed consent?
(	Yes	No
		e severely injured and bleeding and were being treated by the paramedics in ity, would you want to be enrolled in this type of study?
(	Yes	No
	by the parame	member of yours were severely injured and bleeding and were to be treated dics, would you want him or her to be enrolled in this type of study?  No  ave any comments or concerns you wish to share with the investigators?
	Age: <u>37</u>	Ethnic background: whit
		ale Female

Please circle your answers

1. Would you support conducting a study such as the one described in this commumeeting, specifically, a study in which severely injured and bleeding patients would enrolled without giving their informed consent?			
ĺ	Yes No		
`	2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?		
	Yes No		
	3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?  No		
	4. Do you have any comments or concerns you wish to share with the investigators?		
_	A		
	Age: 32 Ethnic background: Quasia		
	Gender: Male Female		

Please circle your answers	
1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?	
Yes No	
2. If you were severely injured and bleeding and were being treated by the paramedics your community, would you want to be enrolled in this type of study?	n
Yes No	
3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?  (Yes) No	ed
4. Do you have any comments or concerns you wish to share with the investigators?	
Benefits for outweigh risks. Life saving benefit	
is going to benefit all.	NCAN'S
	pathaba TTROV
Age: 58 Ethnic background: Chuckschin	
Gender: Male Female	
	-

Please circle your answers

meeting, spec	u support conducting a study such as the one described in this community cifically, a study in which severely injured and bleeding patients would be out giving their informed consent?
Yes	No
	re severely injured and bleeding and were being treated by the paramedics in nity, would you want to be enrolled in this type of study?
Yes	No
•	member of yours were severely injured and bleeding and were to be treated edics, would you want him or her to be enrolled in this type of study?
Yes	No
4. Do you h	nave any comments or concerns you wish to share with the investigators?
Age: <u>3'0</u>	Ethnic background: Jaucasian
Gender: M	ale Female
·	TILL 1 Co

	Piease circle	your answers
	meeting, spec	support conducting a study such as the one described in this community ifically, a study in which severely injured and bleeding patients would be out giving their informed consent?
(	Yes	No
	2. If you were your commun	e severely injured and bleeding and were being treated by the paramedics in ity, would you want to be enrolled in this type of study?
(	Yes	No think-see commentary
(	yes low	member of yours were severely injured and bleeding and were to be treated edics, would you want him or her to be enrolled in this type of study?  Sold comments No
	I'm m	ave any comments or concerns you wish to share with the investigators?
	_stuff.	once blood is qualable I'm the hospital
	_but ]	E throne research in this area is good
	Age: <u>39</u>	Ethnic background: Cautasian
	Gender: M	ale Female

Please circle	e your answers
meeting, specenrolled with	ou support conducting a study such as the one described in this community cifically, a study in which severely injured and bleeding patients would be nout giving their informed consent?
Yes	No
	re severely injured and bleeding and were being treated by the paramedics in nity, would you want to be enrolled in this type of study?
Yes	No
•	y member of yours were severely injured and bleeding and were to be treated aedics, would you want him or her to be enrolled in this type of study?
Yes	No
4. Do you l	have any comments or concerns you wish to share with the investigators?
	/_//
Age: <u>32</u>	Ethnic background: b/ack
Gender: M	fale <u>\( \sum_{</u>

# Please circle your answers 1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent? Yes No 2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study? No Yes 3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study? Yes No 4. Do you have any comments or concerns you wish to share with the investigators?

Thank you for your participation today. Please call Arletta VanBreda at 703-504-3071 if you have any other questions.

Ethnic background: \_\_\_\_\_\_\_\_\_\_\_

Male Female

#### POLYHUME COMMUNITY MEETING FRANK FORM

#### Please circle your answers

meeting,	specifically,	t conducting a study such as the one a study in which severely injured aring their informed consent?	
Yes	No		
		ely injured and bleeding and were be ald you want to be enrolled in this ty	
Yes	No		
		er of yours were severely injured and ould you want him or her to be enrol	
Yes	No		
		comments or concerns you wish to	share with the investigators?
Age:			
Gender:	Male	Female	
		Thank you for your participation	

Please call Arletta VanBreda at 703-504-3071 if you have any other questions.

# 1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent? Yes No

Please circle your answers

enrolled without giving their informed consent?
Yes No
2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?  Yes  No  No  No  No  No  No  No  No  No  N
Some concerne about receive polytoneme versus.  Short in the pospore.
Age: 50 Ethnic background: Culinau
Gender: Male Female

Thank you for your participation today. Please call Arletta VanBreda at 703-504-3071 if you have any other questions.

# FOUTHERS COMMUNITY MEETING FEEBACK FORM

Please circle your answ	vers
meeting, specifically, a	conducting a study such as the one described in this community study in which severely injured and bleeding patients would be their informed consent?
Yes No	
	y injured and bleeding and were being treated by the paramedics in d you want to be enrolled in this type of study?
Yes No	
	of yours were severely injured and bleeding and were to be treated ald you want him or her to be enrolled in this type of study?
Yes No	
4. Do you have any c	omments or concerns you wish to share with the investigators?
Age:	Ethnic background:
Gender: Male	Female
	<u>.                                  </u>
	Thank you for your participation today.

Please call Arletta VanBreda at 703-504-3071 if you have any other questions.

riease circle your unswers
1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?
(Yes) No
2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?
Yes No
3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?
Yes No
4. Do you have any comments or concerns you wish to share with the investigators?
Age: 42 Ethnic background:

Thank you for your participation today.

Please call Arletta VanBred at 703-504-3071 if you have any other questions.

Gender: Male \_\_\_\_ Female \_\_\_\_\_

Please circle your answers
1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?
Yes No
2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study?
Yes No
3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?
Yes No
4. Do you have any comments or concerns you wish to share with the investigators?
Age: 39 Ethnic background: 6
Gender: Male Female

#### FEEDBACK FORM

Age: \_\_50\_\_\_

Gender:

Download and save this Microsoft Word	document. Fi	ill out the	document,	and e-
mail it to Arletta.vanbreda@inova.com.				

1. Would you support conducting a study such as the one described in this community,
specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent? (Type Yes or No in the space below)
YES-
2. If you were severely injured and bleeding and were being treated by the paramedics in your community, would you want to be enrolled in this type of study? (Type Yes or No in the space below)
YES
3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study? (Type Yes or No in the space below)
YES
4. Do you have any comments or concerns you wish to share with the investigators?

Thank you for your participation today. Please call Arletta VanBreda at 703-504-3071 if you have any other questions.

Ethnic background: Caucasian\_\_\_\_

Male \_\_\_\_ Female \_X\_\_\_

	Please circle your answers			
	1. Would you support conducting a study such as the one described in this community meeting, specifically, a study in which severely injured and bleeding patients would be enrolled without giving their informed consent?			
(	Yes No			
	2. If you were severely injured and bleeding and were being treated by the paramedi your community, would you want to be enrolled in this type of study?			
	Yes No .			
	3. If a family member of yours were severely injured and bleeding and were to be treated by the paramedics, would you want him or her to be enrolled in this type of study?			
(	Yes No			
4. Do you have any comments or concerns you wish to share with the investig				
•				
	Age: 51 Ethnic background: Ameri Sad			
	Gender: Male Female			

# POLYHEME MEDIA INQUIDUES

Date	Media Outlet	Result
3/3/05	WRC Channel 4	Story 3/7/05
3/3/05	Washington Business Journal	Story 3/25/05
3/4/05	Metro Radio Networks	Story 3/7/05
3/4/05	WUSA Channel 9	Story 3/7/05
3/4/05	Washington Examiner	Story 3/8/05
3/7/05	WTTG Channel 5	Story 3/7/05
3/7/05	WAMU Radio 88.5 FM	Story 3/7/05
3/8/05	Kojo Nnamdi Show (WAMU)	Story 3/10/05
3/9/05	Connection Newspapers	Story 3/17/05